

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**REMARKS/ARGUMENTS**

All of the claims originally in the application, comprising claims 1-17, stand rejected under 35 U.S.C. §§102 or 103. Claim 2 has been canceled, rendering its rejection moot. The rejection of remaining claims 1 and 3-17 is respectfully traversed for the reasons stated herein.

Claims 1-8, 11, and 16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ohnishi et al. U.S. Patent No. 5,244,578 ("Ohnishi"), the Examiner reasoning that each of the limitations in those claims is fully disclosed by Ohnishi. With respect, applicants disagree.

Claim 1 is the only independent claim in the application, with all of the remaining claims ultimately depending therefrom and so containing the same limitations. Accordingly, if claim 1 is distinguishable from the prior art relied upon, all of the remaining claims are likewise distinguishable.

Claim 1 as amended is directed to a device for the simultaneous separation of particles and at least one target substance, wherein the device has a permeate outlet for the discharge of permeate that is substantially free of target substance(s) and is provided with membrane layers having apertures therein that permit the passage of particles that are present in the liquid feed, the absorption membranes carrying at least one binding group that is capable of binding the target substance, the binding group being a functional group, a ligand or an ion exchange site. This claim is readily distinguishable from the disclosure of Ohnishi, as will be shown below.

Ohnishi is directed to a blood plasma-separating membrane wherein the membrane comprises a hydrophobic polymeric substrate such as a polyolefin coated with a hydrophilic polymer that is either a homopolymer or a copolymer of an alkoxyalkyl methacrylate or a copolymer of a hydrophilic monomer with a hydrophobic monomer. See column 2, lines 50-62. The Examiner asserts that Ohnishi's membranes are "adsorption" membranes, pointing to column 1, line 63 through column 2, line 5. The Examiner is respectfully submitted to be mistaken. First, the excerpt of Ohnishi relied upon by the Examiner refers not to the Ohnishi invention, but to Japanese Patent 62-290,469, and specifically to the drawback of the invention disclosed in that patent, i.e., that the same causes hemolysis or destruction of the red blood cells on the surface of the prior art membrane. In any event, a membrane that causes hemolysis of red blood cells is certainly not an "adsorption" membrane as claimed by applicants in claim 1, i.e., one containing a particular class of binding groups.

The Examiner also points to Ohnishi at column 5, lines 1-22 to support the contention that the membrane layers of Ohnishi carry a group capable of binding a target substance, the group being selected from a functional group, a ligand and an ion exchange site. However, a careful review of column 5, lines 1-22 of Ohnishi reveals that there is no mention whatsoever of any binding of any target substance to the membrane, nor any mention of a functional group, a ligand, or an ion exchange site on or in the membrane layers. To the contrary, the only functional group mentioned by Ohnishi is a hydroxy group, which Ohnishi states very clearly should be avoided in the membrane that is used to contact the blood being treated. See column 5, lines 27-31.

The Examiner further contends that Ohnishi's membrane layers contain apertures that permit the passage of particles present in the liquid feed. Again, a careful reading of Ohnishi shows that this is not the case. Specifically, the operation of the Ohnishi blood plasma-separating membrane unit is discussed at column 8; significantly, at lines 28-30 and 55-60, it is very clearly stated that the orifices 49 in the membrane layers function as blood plasma-passing orifices and that the blood cells are discharged through blood outlet 43. Bearing in mind that blood plasma is that portion of blood remaining after removal of its cellular components (see the enclosed definition of blood plasma from Hawley's Condensed Chemical Dictionary), it is seen that the Ohnishi orifices 49 function to allow passage of that portion of the blood feed that does not contain cells (or particles), while the blood cell-containing portion remains behind, to be discharged through blood outlet 43. Thus, the Ohnishi device has membranes with orifices that do not permit the passage of particles, as claimed by applicants in claim 1.

Applicants also respectfully take issue with the Examiner's contentions concerning Ohnishi supposedly disclosing the limitations of claims 7-8. Specifically, the Examiner contends that Ohnishi discloses spacers of materials that may be characterized as a web, a mesh, a woven material, or a matting, pointing to Ohnishi's elements 67 and 77, and to column 9, lines 5-10 and column 7, lines 58-65. Element 67 is not identified in the Ohnishi patent; to the extent the Examiner disagrees, applicants respectfully request the Examiner to point out the exact location where the identity of element 67 is given. As to spacer 77, Ohnishi states, at column 9, lines 7-10, that the same is a "sheetlike article provided on both surfaces thereof with minute projections as illustrated in FIG. 1A and FIG.

1C.” Thus, Ohnishi’s own description taken with his FIGS. 1A and 1C, does not qualify spacer 77 as a web, a mesh, a woven material, or a matting.

As to claim 8, the Examiner asserts that the apertures in the adjacent membrane layers of Ohnishi are offset from each other, pointing to FIGS. 3-4 and to column 8, lines 10-47. But neither FIG. 3 nor FIG. 4 show any offset arrangement, and there is simply no support seen for the Examiner’s position at column 8, lines 10-47.

In any event, since claims 3-8, 11 and 16 all ultimately depend from claim 1, which is distinguishable from Ohnishi for the reasons stated above, all of those claims are likewise distinguishable.

Claims 9-10 and 12-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnishi, the Examiner reasoning that, although Ohnishi does not teach the specific membrane aperture areas and dimensions claimed in claims 9-10 and 12-13, it would be obvious to one of ordinary skill that those areas and dimensions could be obtained by proper optimization of design. With respect, the fundamental drawback to the Examiner’s position is that there is nothing in Ohnishi that teaches anything about varying the area or dimensions of apertures in the membranes, nor how or why they are to be varied. With no such suggestions or guidelines in the Ohnishi reference, there is no motivation for one of ordinary skill in the art to alter the area or dimensions of the apertures. To the contrary, if one did alter the dimensions of the apertures in the Ohnishi membranes so as to allow blood cell components to pass through, this would destroy the function of the Ohnishi device which is to recover blood cell components from blood cell outlet 43.

Finally, claims 14-15 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnishi in view of Le et al. U.S. Patent No. 4,895,806 ("Le"), the Examiner reasoning that Le teaches the use of a spiral-wound membrane in a module as claimed in claims 14-15, and the membrane pore size as claimed in claim 17, and that therefore it would be obvious to one of ordinary skill to modify the Ohnishi blood plasma-separating device with the relied upon disclosures of Le. In response, applicants point out that the Ohnishi device is a device for separating cellular components (white blood cells, red blood cells, and platelets) from a fluid (whole blood) while Le discloses a device for separating molecular components from liquids. One of ordinary skill would readily understand, at the minimum, the immense difference in scale between, e.g., white blood cells and molecules. Thus, it is highly questionable whether the disclosures of Ohnishi and Le are compatible inasmuch as the objects of the two inventions are so radically different. Given this incompatibility, it is respectfully submitted that one of ordinary skill would have no motivation to combine the features of Le with those of Ohnishi. Nevertheless, conceding for purposes of argument that the teachings of Ohnishi and Le are compatible, since claims 14-15 and 17 all ultimately depend from claim 1, and since claim 1 is distinguishable from the primary reference Ohnishi for the reasons stated above, claims 14-15, and 17 are likewise distinguishable from Ohnishi.

Application No. 09/936,065  
Amdt. dated November 5, 2003

For the reasons stated, early and favorable reconsideration is respectfully  
solicited.

Respectfully submitted,



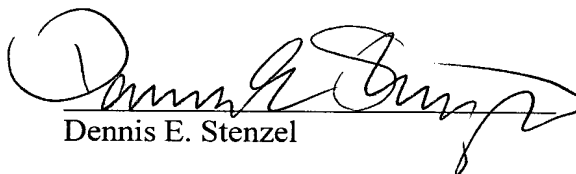
Dennis E. Stenzel  
Reg. No. 28,763  
Of Attorneys for Applicant  
Tel: (503) 227-5631

#### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: \_\_\_\_\_

Nov 5 '03



Dennis E. Stenzel